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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/734,011	12/11/2003	Teruo Miyazaki	F-8074	2363
28107	7590	08/23/2004	EXAMINER	
JORDAN AND HAMBURG LLP 122 EAST 42ND STREET SUITE 4000 NEW YORK, NY 10168			KOSSON, ROSANNE	
			ART UNIT	PAPER NUMBER
			1651	

DATE MAILED: 08/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/734,011

Applicant(s)

MIYAZAKI, TERUO

Examiner

Rosanne Kosson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>12 / 11 / 03</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for stimulating the immune system of flounders to control infection by *Edwardsiella tarda*, does not reasonably provide enablement for a substance "activating biological functions" in fish and shellfish. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. A substance that activates a biological function in a fish or shellfish is broad enough to encompass one that, for example, stimulates growth of the fish or shellfish, or increases fertility or increases swimming speed. Thus, while the specification teaches a substance that activates the immune system of one type of fish, so that that fish produces antibodies that fight one type of bacterial infection, the specification does not teach a substance that activates any biological function in fish or shellfish. One of ordinary skill in the art would have no indication as to what sort of substances would be effective in activating any other biological function, even stimulation of the immune system in a different type of fish, for example, tuna, to fight infection by a different

microbial pathogen. The specification provides no specific guidance for identifying or isolating such substances. Thus, a holding of non-enablement is required.

Additionally, claim 2 recites that the substance activating the biological function may be an inactivated pathogenic virus or bacterium or a pulverized endoparasite. As noted above, the specification, while being enabling for stimulating the immune system of flounders to control infection by *Edwardsiella tarda*, does not reasonably provide enablement for a substance that is an inactivated pathogenic virus or other bacterium or a pulverized endoparasite. The specification provides no specific guidance for the formulation of additives containing these organisms, nor does it provide any evidence that administering such an additive, or a feed containing or coated with such an additive would effectively control infection by one or more of these organisms. Thus, a holding of non-enablement is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 6, 7 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The first step of claims 5 and 7, which recites the phrase "pretreating for preparing powder, an aqueous solution or suspension ..." is unclear because it cannot be determined from the claims or from the specification what the pretreatment is. How and with what is the biologically active substance pretreated? Applicant may wish to amend the claims by deleting the words "pretreating for." The

third step of claims 5 and 7, which recites separating the oil into myriads of oil microglobules, is unclear because the word "myriads" is a relative and indefinite amount. How many microglobules are myriads? Applicant may wish to amend the claims by deleting the words "myriads of."

Claim 9 recites that the biologically active substance is in an aqueous solution or suspension in the pretreatment step. As discussed above, no pretreatment step has been defined. Thus, this phrase renders the claim unclear.

Claim 6 recites the limitation "wherein the stirring is performed" There is insufficient antecedent basis for this limitation in the claim.

A holding of indefiniteness for claims 5, 6, 7 and 9 is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4 are rejected under 35 U.S.C. 102(b) as being anticipated by Villamar et al. (WO 02/00035). Villamar discloses an additive for fish and shellfish feed that is an emulsion comprising edible oil globules, wherein the oil globules contain a substance that enables a fish or shellfish to fight infection by a microorganism from which the substance is derived. The substance may be inactivated bacterial or yeast cells or fractions thereof. The additive may comprise water and may be formulated to be

sprayed on or to coat dry pellets of feed (see p. 8, last paragraph, p. 11, last full paragraph; p. 12, 2d full paragraph; p. 16 first two full paragraphs; p. 17, first full paragraph; p. 18, first full paragraph and paragraph bridging pp. 18 and 19). With regard to oil microglobules less than 10 μ in diameter, Villamar discloses that the second emulsion, containing an aqueous phase, may be atomized into microcapsules of 20-200 μm , or 0.02-0.2 μ . These microcapsules contain particles of the oil substance-containing phase that are, therefore, less than 10 μ in diameter (see p. 17, first full paragraph). Accordingly, a holding of anticipation is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Villamar et al. (WO 02/00035). As discussed above, Villamar discloses an additive for fish and shellfish feed that is an emulsion comprising edible oil globules, wherein the oil globules contain a substance that enables a fish or shellfish to fight infection by a microorganism from which the substance is derived. The substance may be inactivated bacterial or yeast cells or fractions thereof. The additive may comprise water and may be formulated to be sprayed on or to coat dry pellets of feed. Villamar also discloses that the second emulsion, containing an aqueous phase, may be atomized into

microcapsules of 20-200 mμ, or 0.02-0.2 μ. These microcapsules contain particles of the oil substance-containing phase that are, therefore, less than 10 μ in diameter (see p. 8, last paragraph, p. 11, last full paragraph; p. 12, 2d full paragraph; p. 16 first two full paragraphs; p. 17, first full paragraph; p. 18, first full paragraph and paragraph bridging pp. 18 and 19).

The emulsion additive is prepared by mixing the solid biologically active substance, such as probiotic bacteria, with a lipid mixture containing fish oil. This mixture is then mixed vigorously. A second emulsion additive is prepared by combining the first additive with an aqueous polymer suspension and mixing vigorously (see p. 20).

Villamar does not disclose separating the oil globules from the emulsion or stirring and sonicating the emulsion with a homomixer to form microglobules. Villamar also does not disclose mixing an emulsion additive with a feed that is in paste form. Nevertheless, such features as preparing an additive containing oil globules rather than one containing an emulsion containing the oil globules and preparing an emulsion with a homomixer rather than with another emulsifier that performs the same function are result-effective parameters which were well known in the art at the time of Applicant's invention to be routinely optimized by one of ordinary skill in the art of preparing animal feeds. Thus, the claimed variations in Applicant's process with respect to these parameters clearly would have been obvious at the time of Applicant's invention, the optimization of these parameters being well within the capabilities of the artisan of ordinary skill at the time of Applicant's invention. Similarly, the feature of kneading an aqueous-phase-containing emulsion, such as the second emulsion disclosed by

Villamar, into a feed in paste form would have been well within the capability of one of ordinary skill in the art. It would have been apparent to the artisan of ordinary skill that a fish or shellfish feed in paste form and used in water does not have a solid outer surface. Thus, a holding of anticipation is required.

Claims 1-9 are also rejected under 35 U.S.C. 103(a) as being unpatentable over Melvin et al. (WO 02/38770). Melvin discloses an oral vaccine for fish to protect fish from bacterial infection in which a biologically active substance, such as inactivated bacteria, may be incorporated into a fish oil with an emulsifier. An emulsion or microparticles containing the biologically active substance may be incorporated into typical fish food and fed to fish. The substance will enter the digestive tract and stimulate an immune response to the substance (p. 11, lines 21-29; p. 13, lines 13-32; p. 14, lines 11-30; p. 15, lines 26-32). The emulsion additive is prepared by mixing the solid biologically active substance, such as inactivated bacteria, with a fish oil containing an emulsifier.

Melvin does not disclose preparing an emulsion containing water or the size of the oil globules. Melvin also does not disclose separating the oil globules from the emulsion or stirring and sonicating the emulsion with a homomixer to form microglobules. Melvin also does not disclose mixing an emulsion additive with a feed that is in paste form.

As discussed above with respect to such features as preparing an additive containing oil globules rather than one containing an emulsion containing the oil

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globules, preparing an emulsion with a homomixer rather than with another emulsifier, and combining the additive with feed in paste form rather than in pellet form, features such as the size of the oil globules and the water content of the emulsion are also result-effective parameters which were well known in the art at the time of Applicant's invention to be routinely optimized by one of ordinary skill in the art of preparing animal feeds. Emulsion additives containing water and oil particles containing various biologically active substances may be combined with fish feed to control microbial infection in fish. Thus, the claimed variations in Applicant's process with respect to these parameters clearly would have been obvious at the time of Applicant's invention, the optimization of these parameters being well within the capabilities of the artisan of ordinary skill at the time of Applicant's invention. Thus, a holding of anticipation is required.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rosanne Kosson
Examiner
Art Unit 1651

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2004-08-13



FRANCISCO PRATS
PRIMARY EXAMINER